

REMARKS/ARGUMENTS

Claims 1-4, 7 and 10-12 have been examined. Claims 1 and 12 have been amended to provide more consistent antecedent support in the claims and remove unnecessary verbiage. New claim 13 is similar to claim 1, but specifically refers to a "damaged" nail or hoof in need of repair, as supported throughout the specification, including at, e.g., page 5, lines 1-2, page 12, lines 9-12, and elsewhere. No new matter has been added.

The claims have been rejected as allegedly obvious under 35 USC § 103(a) in view of Pickart, U.S. Patent No. 5,382,431 (the '431 patent). According to the Office, even though Pickart does not teach stimulating the growth of fingernails, toenails and hooves in a mammal, the '431 patent does teach the same composition. Thus, allegedly, it would have been obvious to use the teachings of the '431 patent, where the composition is said to be useful for stimulating the healing process of the skin and stimulating hair growth, in the methods of the present invention.

The rejection is respectfully traversed. The '431 patent teaches administering the compositions of peptide-metal complexes to the skin, whether it be to facilitate wound healing, prevent oxidative damage to the skin, or to stimulate hair follicles. Although the compositions may be administered by a variety of routes, ultimately the target, e.g., a wound, hair follicle, etc., is located on or in the skin. There is no suggestion that the compositions might be useful for treatment of damaged nails.

Indeed, nails and hooves are substantially different from skin with respect to chemical and structural composition and permeability. Although nail material is similar to the stratum corneum of the skin, being derived from epidermis, it is composed primarily of hard keratin, has a high sulphur content, and is highly cross-linked. Nitrogen is the major component of the nail, attesting to the nail's proteinaceous nature. The total lipid content of mature nail is

0.1 to 1.0%, whereas, in contrast, the stratum corneum of the skin has a lipid content of about 10% w/w. In humans, the nail is about 100-200 times thicker than the stratum corneum (which is about 10-15 cells thick). In hoofed animals, of course, the nail is many times thicker than the nail of a human. The thick, hard, and dense nail plate represents a formidable barrier for drugs to be able to penetrate in a therapeutically required quantity. For many drugs, to deliver a sufficient amount of drug into the nail plate the permeability of the nail plate to the drug must be enhanced.

Other significant differences exist between nails and skin such that the success achieved by the methods of the present invention with nails could not have been predicted based on the teachings of the Pickart '431 patent regarding skin. For example, skin is a vascularized tissue, characterized by the presence of blood and lymph vessels, nerves, immune cells, muscles around hair follicles, sweat glands, oil glands, etc. Nails have no internal systems such as blood or lymph vessels, no immune cells, no muscle cells, no sweat or oil glands, etc., (though the nail bed itself adds materials to the underside of the nail plates to make it thicker and remain healthy). In view of the differences between the two tissues, the person of ordinary skill could not have extrapolated the successful methods described in the present application relating to nails based on the results attained in the '431 patent relating to treatment of skin wounds, stimulating hair follicle growth, etc.

Accordingly, the present claims are not suggested by, and are non-obvious over, the teachings of the '431 patent, and Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. In the event the claims are determined by the Examiner to be

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allowable, including the generic claim(s), Applicant respectfully requests consideration of the additional species claims which depend directly or indirectly from the generic claim, as provided by 37 C.F.R. § 1.141.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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